510(K) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:	SeaSpine, Inc. Contact: Kirt Stephenson 6276 River Crest Drive, Suite E Riverside, CA 92507-0754 Phone: 909-656-4850 Fax: 909-656-5530
Company Registration Number:	2032593
Submission Correspondent:	The Regulatory Affairs Company Contact: Diana Smith 727 Park Boulevard San Diego, CA 92101 Phone: 619-251-9132 Fax: 619-696-9883
Date Summary Prepared:	April 7, 2003
Classification Name:	Spondylolisthesis Spinal Fixation Device System (Class II) – MNH 888-3070 Pedicle Screw Spinal System (Class II) – MNI 888-3070 Spinal Interlaminal Fracture Orthosis (Class II) – KWP 88-3050
Common/Usual Name:	Laminar and Pedicle Hook Assemblies and Instruments
Device Trade Name:	UCR Spinal System

The primary devices used for comparison in this summary are Cross Medical Products' *Synergy™ Posterior Spinal System* and Medtronic Sofamor Danek's *CD Horizon™*.

1. **Intended Use:** (The statements of intended use are identical.)

The intended use of the UCR Spinal System hooks and their components is substantially equivalent to the intended use of the predicate devices. The intended use of the UCR Spinal System and hooks is as a temporary or permanent posterior implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusions to occur.

The intended use and indications when used as a **Spondylolisthesis Spinal Fixation Device System** are:

- **The UCR Spinal System** is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The intended use and indications when used as a **Pedicle Screw Spinal System** are:

- **The UCR Spinal System** is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor, and
- failed previous fusion (pseudoarthrosis).

Hook Spinal System indications are limited to T1-L5 and are:

- degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history ad radiographic),
- spinal stenosis,
- spondylolisthesis,
- spinal deformities (scoliosis, kyphosis, and/or lordosis),
- fracture,
- pseudarthosis,
- tumor resection, and/or
- failed previous fusion.

2. Description:

The UCR Spinal System hooks include titanium alloy laminar and pedicle hook assemblies. The laminar hooks will be available in widths of 5.5mm and 7.0mm and in five heights that range from 5.0 to 10.0mm. The pedicle spinal hooks will be available in widths of 7.5mm and 9.0mm and in four heights that range from 5.0 to 9.5mm. The laminar hooks will also be available in offset versions. The hook assembly is comprised of a hook body, temporary fixation pin, cap, and set screw. The hook assembly is designed to be compatible with and work in conjunction with the components in the current UCR Spinal System. The product is supplied "NON-STERILE" and must be sterilized prior to use

The UCR Spinal System hooks also utilize a variety of instruments to assist in placement of the devices. These instruments include a hook holder, hook inserter,

temporary fixation pin inserter, power rod gripper, and a rocker. The instruments will be fabricated from stainless steel and Radal. The product is supplied "NON-STERILE" and must be sterilized prior to use.

3. Technological Characteristics:

The hook assembly has been designed as an addition to the current UCR Spinal System. The hook system is new to the UCR Spinal System line, but has substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material.

4. Comparison Analysis:

The overall design of the UCR Spinal System hooks and their components are substantially equivalent to the predicate devices. See **Table 1** on the following page for a comparison of the UCR Spinal System hooks and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2003

SeaSpine, Inc.
c/o Ms. Diana Smith
Principal
The Regulatory Affairs Company
727 Park Boulevard
San Diego, California 92101

Re: K031381
Trade/Device Name: UCR Spinal System
Regulatory Number: 21 CFR 888.3070 (b)(1), 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: April 16, 2003
Received: May 1, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

UCR Spinal System

Indications for Use Statement

510(k) Number (if known): K031381

Device Name: UCR Spinal System

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The intended use and indications when used as a **Spondylolisthesis Spinal Fixation Device System** are:

- **The UCR Spinal System** is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The intended use and indications when used as a **Pedicle Screw Spinal System** are:

- **The UCR Spinal System** is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor, and
- failed previous fusion (pseudoarthrosis).

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031381

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR § 801.109)

Indications for Use Statement continued

Hook Spinal System indications are limited to T1-L5 and are:

- degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history ad radiographic),
- spinal stenosis,
- spondylolisthesis,
- spinal deformities (scoliosis, kyphosis, and/or lordosis),
- fracture,
- pseudarthosis,
- tumor resection, and/or
- failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR § 801.109)